the group consisting of CSF-1, GM-CSF, SF, G-CSF, EPO, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, IL-14, IL-15, GM-CSF/IL-3 fusion proteins, LIF and FGF.

53. (New) A method according to claim 51, wherein the patient is receiving AZT therapy.

REMARKS

The Abstract has been amended to be accurate to the claimed invention. Claims 33-35, 37-41, and 49-53 are pending. Claim 33 is amended to more particularly define and distinctly claim what applicants consider as their invention. New claims 49-53 are added to replace the canceled claims 42-48.

Applicants will address the individual rejections that were present in the parent application Serial No. 08/444,625, as they apply (or do not apply) to the instant claims.

I. Rejection Under 35 U.S.C. §103

The claims stand rejected under 35 U.S.C. §103 as allegedly being obvious over U.S. Patent Nos. 5,192,553 to Boyse et al.; in view of 5,199,942 to Gillis and Lyman et al., (Cell, 1993). The USPTO alleges that:

> Boyse et al. teach the use of hemopoietic stem and progenitor cells including transfected cells as well as autologous cells in reconstituting the hemopoietic system in numerous conditions. The reference is silent about the use of flt3-L as well as other cytokines in the stimulation and maintenance of said hemopoietic cells. [emphasis added]
>
> Gillis teaches the use of numerous cytokines encompassing those claimed, including combinations of said hemopoietic cytokines, in the stimulation and maintenance of hemopoietic cells employed in bone marrow transplantation.
>
> Lyman et al. teach the flt3-L and its ability to stimulate hemopoietic stem or progenitor cell populations. *** One of ordinary skill in the art at the time the invention was made would have been motivated to substitute or use in combination the hemopoietic cytokine flt3-L, as taught by Lyman et al., to stimulate and maintain hemopoietic cells both in vitro and in vivo for the art-known hemopoietic requirements encompassed by the claims.

Applicants disagree with the USPTO's rejection. The USPTO's theory that one skilled in the art might be motivated to try to do what applicants have accomplished amounts to speculation and an impermissible hindsight reconstruction of applicants' claimed invention.

Boyse et al. disclose the collection of neonatal hematopoietic or stem cells, followed by the cryopreservation of such cells for future use. As the USPTO has stated, Boyse et al. do not disclose the use of the claimed human flt3-L, which is a required part of applicants' claims. Boyse et al. provide no suggestion to use human flt3-L as claimed by applicants. Boyse et al. suggest use of IL-3, GM-CSF, IL-4 or IL-6 to expand such cells (col. 22, lines 34-54).

Gillis discloses the use of GM-CSF, G-CSF, IL-3, IL-1, SF, and GM-CSF/IL-3 fusions in autologous transplantation. Gillis' procedure is used to ex vivo expand the hematopoietic cells after they have been collected and to return them to the patient after cytoreductive therapy. No disclosure or suggestion to use the specific cytokine flt3-L, as claimed by applicants, is made. Furthermore, Gillis does not disclose the use of the cytokines as claimed in claim 33 subparts (i) or (iii). Gillis can not be said to render applicants' claims obvious.

Lyman et al. discloses the cloning of murine flt3-L and its potential for use in stimulating the proliferation of hematopoietic stem and progenitor cells. Lyman et al. do not disclose the cloning or isolation of human flt3-L as claimed by applicants.

Taken together, or alone, the cited documents provide the following disclosures. The collection of fetal or neonatal hematopoietic stem or progenitor cells (Boyse et al.), the potential in vitro expansion of such cells with IL-3, GM-CSF, IL-4 or IL-6 (Boyse et al.); the use of cytokines GM-CSF, G-CSF, IL-3, IL-1, SF, and GM-CSF/IL-3 fusions for autologous transplantation (Gillis); and the cloning of murine flt3-L (Lyman et al.). Nowhere do the cited documents provide the nexus needed to render applicants claimed use of the human flt3-L as obvious. It may have been obvious to try to find and clone the human flt3-L, but as disclosed by Lemischka in the earlier papers in this record, Lemischka failed in his attempts to clone the human homologue. Being "obvious to try" is not the standard of the law for §103 obviousness. Applicants respectfully submit that the USPTO has failed to establish the required prima facie case of obviousness. Withdrawal of the rejection is requested for all claims.

II. Rejection Under 35 U.S.C. 103

The claims stand rejected under 35 U.S.C. §103 as allegedly being obvious over U.S. Patent Nos. 5,192,553 to Boyse et al.; 5,199,942 to Gillis in view of Hannum et al. (Nature 1994).

Applicants have above discussed the disclosures and inapplicability of the two patent documents to the claimed invention. Hannum et al. was not published until 1994 and does not constitute prior art against the claims as amended.

In summary, applicants have shown that the claims are in condition for allowance and respectfully request the issuance of a favorable action upon reconsideration.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: BOX SEQUENCE, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date indicated below.

Date: Dec. 18, 1997 Signed: Nancy M. Kenton